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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,327	09/17/2003	Edmund Schiessle	SSHP0101PUSA	4212

22045 7590 12/05/2006

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EXAMINER

HOLMES, REX R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,327	Applicant(s) SCHIÉSLE ET AL.	
	Examiner Rex Holmes	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 7-8 recite the limitation "visual display means" in lines 1-2 of the claims. There is insufficient antecedent basis for this limitation in the claim.
4. Regarding Claims 9 and 13, each recite the limitation, "... comprising ...", this expands the previous claim instead of further limiting it. It is suggested that the applicant use "further comprising."
5. Claim 10 recites the limitations "said microcontroller" in lines 1-2 and "said preamplifier" in line 2. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 11 recites the limitations "said microcontroller" in lines 1-2 and "said A/D converter" in line 2. There is insufficient antecedent basis for this limitation in the claim.
7. Claims 13-15 recite the limitation "said warning signal generating means" in line 2 of claim 13 and line 1 of claims 14-15. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilham (U.S. Patent No. 5,622,178) in view of Kamen (U.S. Patent No. 5,682,901) and further in view of Levitan et al. (U.S. Patent No. 6,731,974).

11. Gilham teaches of a system and method for dynamically displaying cardiac interval data using scatter-plots, that can be used for the detection of atrial fibrillation (col. 15 lines 41-44). Gilham further teaches of the system comprising an interval monitor calculates first and second cardiac intervals corresponding to a period of time between first and second heartbeats and the second interval corresponding to a period of time between the second heart beat and a third heartbeat (col. 2 lines 10-16).

Gilham also teaches of a display having first and second axes labeled with a plurality of indicators corresponding to time intervals, that displays the first and second intervals as a coordinate pair (col. 2 lines 21-27). Gilham further teaches of using successive RR intervals (col. 5 lines 65-67, col. 6 line 1).

12. Gilham also teaches of the system including a heartbeat analyzer that determines a clinical type for the heartbeats (col. 2 lines 33-42). Gilham further teaches of a system for evaluating scatter-plot data comprising stored data corresponding to a predefined normal pattern, in which a comparison is made between the measured scatter-plot data and the stored scatter-plot data (col. 4 lines 21-27). Gilham also teaches of the system being able to alert the user of the presence of clinical abnormality, for example atrial fibrillation (col. 15 lines 39-45). Gilham teaches of calculating an electronic scatter plot (col. 15 lines 41-44), which is inherently a virtual display as it is created by a computer system.

13. Kamen teaches of an apparatus and method for measuring autonomic activity of a patient, that comprises obtaining ECG signals, measuring the R-R interval and generating a Poincare plot from the R-R signals (col. 2 lines 11-18). Kamen further teaches of quantifying the degree of heart failure the patient may be experiencing (col. 2 lines 23-32). Kamen further teaches of identifying geometrical point patterns in the Poincare plots as an indication of the patient's health state (col. 9 lines in 24-38).

14. Levitan et al. teaches of a method and system for measuring heart rate variability, that comprises a obtaining and recording heartbeat-to-heartbeat intervals, during a predetermined period of time, generating a recurrence plot form the intervals

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and calculating a determinant (col. 3 lines 17-35). Levitan further teaches of classifying a patient by assigning a degree of risk for death due to heart failure (col. 3 lines 9-16).

15. Examiner takes the position that although Gilham does not explicitly teach of using geometrical point patterns/structures for the purpose of identifying conditions, as taught by Kamen, it would have been obvious to one having ordinary skill in the art to modify the system of Gilham to add such a feature to provide an enhanced capability of identifying conditions. Additionally, although Gilham does not explicitly teach of using electronic checking of a generating scatter plot, as suggested by Levitan et al., it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system of Gilham to include such a feature to enhance the detection of a condition.

16. Regarding the use of analog circuits, that include preamplifiers, electronic filters and a main amplifier are commonly used in this art for obtaining measured signals. Further, digital circuits that include an A/D converter, a microcontroller, memory and stages for sampling are also commonly used in connection with analog circuits in this art. The use of batteries with audio or visual low voltage warning indicators is also commonly in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Gilham to include analog and digital circuits, as well a battery with a low voltage indicator in order to provide efficient and safe operation of the system.

17. Further, Applicant is not claiming the visual display is a state signal; therefore, Examiner is of the position that any display that represents results of an electronic

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check could be used, which would include the visual results as suggested by Levitan et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Gilham, Kamen and Levitan et al., to have the limitations of claims 7-17.

18. Examiner notes the limitation, "... being capable of assuming at least three values representative of at least three degrees of deviation of said characteristic distribution from said normal distribution", is only functional language and only requires the capability to so perform. Here the visual results as suggested by Levitan et al. are capable of being used to display at least three values representative of at least three degrees of deviation of said characteristic distribution from said normal distribution.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

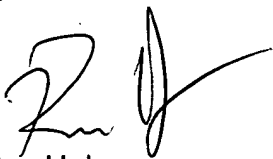
- Griffin et al. (U.S. Pub. 2002/0052557 A1) – discloses a method of monitoring a patients RR intervals, generating a data set and identifying abnormal heart rates.
- Ohsuga et al. (U.S. Pat. 4,896,675) – discloses an apparatus for monitoring a patient including a R-wave detector, CPU, memory, LCD, Measuring state LED's and a means for plotting data and displaying result values on the LCD screen.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes



George Evanisko

Primary Examiner

11/30/16